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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/560,289	05/26/2006	Robert J Benkowski	021906-024US	3187

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EXAMINER

NARAYANASWAMY, SHUBATRA

ART UNIT	PAPER NUMBER
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3762

NOTIFICATION DATE	DELIVERY MODE
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08/19/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

hoip@lockelord.com

Office Action Summary	Application No. 10/560,289	Applicant(s) BENKOWSKI ET AL.	
	Examiner SHUBATRA NARAYANASWAMY	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 July 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2031 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

Claim Rejections - 35 USC § 101

2. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 20-31 are rejected under 35 U.S.C. 101 because the claimed method is not tied to a particular structure. The steps of performing a time/frequency analysis must be tied to a specific structure or machine.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 20-31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification appears to be silent regarding the method step of analyzing the flow waveform in both the time domain and frequency domain.

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 20 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 7,396,327. Although the conflicting claims are not identical, they are not patentably distinct from each other because both claims are directed to obvious variations of controlling a blood pump by analyzing a flow waveform or signal in both a time domain and a frequency domain.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 20, 22, 26-29, and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Smith (US 4989609).

As to claim 20, Smith discloses a method of controlling a blood pump, comprising:

receiving, in a controller, a flow signal from an implanted flow sensor, the flow signal indicative of an instantaneous flow waveform;

analyzing the flow waveform in both the time domain and frequency domain; and
outputting, from the controller, a control signal to control an implanted blood pump in response to the analysis of the flow waveform (Figs. 3, 7; col. 8 ll. 1-35).

As to claim 29, Smith discloses the method of claim 20 further comprising analyzing the flow waveform based on both instantaneous and mean values (abstract).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 21, 23-25 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith (US 4989609) in view of Hertz (US 6090048).

As to claims 21 and 25 Smith discloses the method of claim 20, but does not specify that the analysis of the flow waveform determines a suction boundary condition.

However, Hertz teaches that the flow waveform determines boundary conditions for suction, maximum speed, minimum speed, and minimum flow (col. 6 ll. 5-25) in order to analyze pulse signals. At the time of the invention, it would have been obvious to one of ordinary skill to modify Smith to include the claimed boundary conditions for suction claimed in order to analyze pulse signals.

As to claim 22, Smith discloses the method of claim 21 where the boundary condition becomes control parameters for closed loop control (Fig. 3).

As to claim 23, Smith discloses the method of claim 21 where the boundary condition causes the control system to limit pump speed, and where upper boundary conditions do not allow the speed to be increased further while lower boundary conditions do not allow the speed to be decreased further (col. 7 ll. 50-70).

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As to claims 24, Smith discloses the method of claim 21 where the boundary condition causes a predetermined decrease in speed then periodically attempts to return to the desired control mode at predetermined intervals (col. 7 ll. 50-70).

As to claim 30, Smith discloses the method of claim 20 but does not specify that the control signal from the controller is adapted to a patient's individual physiology in response to suction detection events. Hertz teaches adapting the control signal to a patient's individual physiology in order to separate the pulse signal from a blood pump signal (col. 7 ll. 50-65). At the time of the invention, it would have been obvious to one of ordinary skill to modify Smith with the method of Hertz. The motivation would have been to separate the pulse signal from the pump signal.

7. Claims 26-28 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith (US 4989609) in view of Benkowski (US

As to claim 26, Smith discloses the method of claim 20, but lacks a safety feature to switch to a Constant Speed mode. Benkowski teaches a safety feature that is automatically enabled in the event the flow signal is lost, erroneous, or compromised (col. 6 ll. 60-col. 7 ll. 11). At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify Smith to include such a safety feature. The motivation would have been to maintain a speed previously determined to be safe.

As to claim 27, Benkowski discloses the method of claim 26 where the quality of the flow signal is determined by the frequency domain analysis of the real-time flow waveform (col. 11 ll. 65-col. 12 ll. 15).

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As to claim 28, Smith discloses the method of claim 20 wherein the control signal from the controller is adapted to a patient's individual physiology, but does not specify that it is adapted in response to speed variations. However, Smith teaches that flow is dependent on speed. Benkowski teaches adapting the control signal in response to speed variations (col. 11 ll. 65-col. 12 ll. 15). At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify Smith with Benkowski. The motivation would have been to maintain a particular amount of flow.

As to claim 31, Smith discloses the method of claim 20 wherein, in addition to controlling the implanted blood pump in response to the analysis of the flow waveform, the controller provides at least one alternative control mode comprising constant speed or constant flow (col. 6 ll. 50-60).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHUBATRA NARAYANASWAMY whose telephone number is (571)-270-7406. The examiner can normally be reached on M-F, 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Niketa Patel can be reached on (571)272-4156. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/George Manuel/
Primary Examiner, Art Unit 3762

/S. N./
Examiner, Art Unit 3762